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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* HARRY LENEAU

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Appeal 2009-003718
Application 10/629,880
Technology Center 1600

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Decided: August 26, 2009

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Before TONI R. SCHEINER, DEMETRA J. MILLS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the Patent Applicant's appeal from the Patent Examiner's rejection of claims 1, 3-10, and 13. Jurisdiction for this appeal is under 35 U.S.C. § 6(b). We reverse.

Statement of the Case

The claims are drawn to methods and compositions "for relieving joint pain or other discomforts associated with joint disorders . . . consisting of" delivering "by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid" and "a food acceptable carrier."

Hyaluronic acid is a mucopolysaccharide found in joint tissue. (Spec. 3: 8.) "Hyaluronic acid functions as a protective coating and a lubricant for soft tissue and joints, and additionally, helps maintain the structural integrity of soft tissue." (*Id.* at 3:9-11.) "In association with protein, hyaluronic acid binds water in the intercellular spaces and holds cells together in a jellylike matrix. This jellylike matrix provides lubrication and shock absorption throughout the body." (*Id.* at 3:11-13.) Hyaluronic acid is a component of cartilage and synovial joint fluid. (*Id.* at 3:15-18.) "The synovial joint fluid provides lubrication for the cartilage against the lining of the joint and may provide some additional shock-absorption value." (*Id.* at 3:18-20.)

Claims 1, 3-10, and 13 are pending and appealed. The Examiner rejected claims 1, 3-10, and 13 under 35 U.S.C. § 102(e) an anticipated by the Pierce patent (U.S. Pat. No. 6,924,273 B2, Aug. 2, 2005) (Ans. 3.)

Claims 1 and 8 are representative and read as follows:

1. A method for relieving joint pain or other discomforts associated with joint disorders in a warm-blooded vertebrate consisting of the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1µg to about 400 µg/kg of body weight.

8. A nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, the nutritional supplement provided in an orally ingestible dosage form.

ISSUE 1

The instant application claims priority back to May 18, 2001 (App. Br. 12). Pierce, which is cited in the § 102(e) rejection against the instant claims, has a provisional application filing date of October 3, 2000 and a filing date of October 2, 2001 for the regular application from which the patent issued. The priority date of the instant application is between Pierce's provisional and regular filing dates. Thus, for Pierce to serve as prior art to the instant application, the disclosure in the Pierce patent relied upon by the Examiner in rejecting the claims, must be enabled by and disclosed in the earlier filed Pierce provisional application. This is the threshold determination at issue in the rejection.

Principles of Law

> In order to anticipate, a prior art disclosure must also be enabling, such that one of ordinary skill in the art could practice the invention without undue experimentation. *SmithKline Beecham*, [403 F.3d 1318,] 1342. . . . Significantly, we have stated that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, Inc., 246 F.3d 1368, 1379 (Fed. Cir. 2001) (citing *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) ("It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.")).

*Novo Nordisk Pharmaceuticals Inc. v. Bio-Technology General Corp*, 424 F.3d 1347, 1355 (Fed. Cir. 2005).

"Attorney's argument in a brief cannot take the place of evidence." *In re Pearson*, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974). "Appellant's opinion on the ultimate legal issue is not evidence in the case . . . [However,] some weight ought to be given to a *persuasively supported* statement of one skilled in the art on what was not obvious to him." *In re Lindell*, 385 F.2d 453, 155 USPQ 521, 524 (CCPA 1967) (emphasis added).

Findings of Fact ("FF")

1. Pierce was filed as provisional application No. 60/237,838 on Oct. 3, 2000 (hereinafter, the "Pierce provisional application" or "Pierce Prov.").

2. The Pierce provisional application describes an oral paste "by the name of Chondrogen EQ" which combines glucosamine sulfate (GS), chondroitin sulfate (CS), and hyaluronic acid (HA). (Pierce Prov. 1.)

3. The paste can be combined with molasses to make it palatable. (Pierce Prov. 7.)

4. The "three substances [in the paste] are the three connective tissue molecules needed to rebuild and synthesize new [connective] tissue." (Pierce Prov. 1.)

5. The Pierce provisional application describes the benefits of oral administration of glucosamine and chondroitin. (Pierce Prov. 3-4.)

6. The Pierce provisional application describes the physiological function of HA and states that its "clinical benefits . . . in the horse are well published." (Pierce Prov. 4.)

7. The Pierce provisional application states: "Generally, the oral administration of embodiments of the present composition has a quicker

clinical response than is produced when *each* component of the composition is *given individually*." (Pierce Prov. 4-5; emphases added.)

8. A paste including HA alone is described in the Pierce provisional application.

> Clinically, responses are seen in 7 to 10 days vs three to four weeks or not at all when GS and CS are given without HA. Therefore, we have seen a dramatic decrease in synovitis when HA is combined with GS and CS. This leads us to conclude that *HA is* absorbed orally and *effective alone* or in combination with GS and CS. *Therefore, an additional embodiment of the invention comprises a composition including HA and any acceptable carrier*, such as the paste formulation disclosed herein and any other liquid, powder, gel or similar type carrier.

(Pierce Prov. 9; emphases added.)

9. Claim 4 of the Pierce provisional application (Pierce Prov. 36) reads as follows:

> 4. A Chondroprotective/Restorative composition comprising Hyaluronic Acid (HA) and optionally a pharmaceutically acceptable carrier.

10. The Pierce provisional patent application describes effective amounts of HA, e.g., 0.18 wt% (Pierce Prov. 7).

Analysis

Claim 1 is directed to a "method for relieving joint pain or other discomforts associated with joint disorders . . . consisting of" delivering "by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid" and "a food acceptable carrier." Claim 8 is to a "nutritional supplement consisting essentially of an effective amount of hyaluronic acid" and "a food acceptable carrier."

The Examiner found that all the limitations of claims 1 and 8 were met by the Pierce patent which describes administering a paste and gel of

HA to mammals (Ans. 3). Appellant does not challenge the Examiner's findings with respect to the Pierce patent. However, Appellant contends that the "invention" disclosed in the Pierce provisional application is "clearly a composition containing glucosamine sulfate, chondroitin sulfate, and hyaluronic acid, and not a composition containing hyaluronic acid alone." (App. Br. 12). Appellant acknowledges that the Pierce provisional introduced and "discuss the concept of oral administration of" of HA, but contends that Pierce "did not enable" it. (*Id.* at 15.) Therefore, Appellant contends that the Pierce patent does not get the benefit of its provisional application filing date and is not prior art to the instant claims.

Appellant's position is not supported by the evidence. As acknowledged by Appellant, the Pierce provisional explicitly discloses and claims a composition comprising HA, alone (FF8-9). The Pierce provisional also describes effective amounts of HA (FF10), providing guidance as to how much HA to administer to achieve a therapeutic effect. The provisional is therefore also enabled for HA administration. Pierce states that the clinical benefits of HA are "well published" (FF6), providing evidence that the persons of ordinary skill in the art would have reasonably believed that Pierce's paste comprising HA, alone, would be effective.

Appellant contends that the statements in the Pierce provisional about a HA composition, alone, is not supported from any other portion of the application and "actually contradicts other statements in the application." (App. Br. 15-16.) The contradiction, according to Appellant, is that the provisional application states:

> Clinically, responses are seen in 7 to 10 days vs three to four weeks or not at all when GS and CS are given without HA.

> Therefore, we have seen a dramatic decrease in synovitis when HA is combined with GS and CS.

(Pierce Prov. 9). Based on this statement, Appellant concludes that the provisional invention is the combination of GS, CS, and HA, not HA alone.

This argument is not persuasive. There are clear statements in the application that HA, alone has clinical benefits (FF6) and would be "effective alone" (FF8). There is also a claim appended to the provisional (FF9), indicating that Pierce considered the HA, alone, as its invention, in addition to it combined with GS and CS.

To establish lack of enablement for an anticipatory reference, there must be evidence that undue experimentation would have been necessary to practice what is disclosed in the reference. *See Novo Nordisk Pharmaceuticals Inc. v. Bio-Technology General Corp*, 424 F.3d at 1355. Here, Appellant has not provided evidence that it would require undue experimentation to make and use a composition comprising HA to treat joint disorders as described in the Pierce provisional application. To the contrary, the evidence militates against such a conclusion (FF6, 8, 9 (claim 4)). That the combination of all three components is better than HA, alone, is not evidence that HA itself would not work. Accordingly, we conclude that the Examiner did not err in concluding that the cited disclosure in the Pierce patent is described and enabled in the Pierce provisional application

ISSUE 2

Appellant submitted a Declaration of Prior Inventorship in the United States under 37 C.F.R. § 1.131 (the "Declaration") to "demonstrate that the subject matter of the Application 'was conceived and reduced to practice at least by the date November 5, 1999, which is a date earlier than the effective

date of U.S. Patent No. 6,924,273 [Pierce], namely October 3, 2000'" (App. Br. 19). Appellant contends that the Declaration is effective to overcome the 35 U.S.C. § 102(e) rejection based on the Pierce patent. (*Id.*)

The Examiner contends that the Declaration is ineffective because Appellant "is claiming the same invention as Pierce" (Ans. 7). The issue is whether the Examiner erred in reaching this conclusion.

## Principles of Law

> 37 C.F.R. § 1.131 Affidavit or declaration of prior invention.
> (a) When any claim of an application . . . is rejected, the inventor of the subject matter of the rejected claim . . . may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. . . . Prior invention may not be established under this section if either:
>
> (1) The rejection is based upon a U.S. patent or U.S. patent application publication of a pending or patented application to another or others which claims the same patentable invention as defined in § 41.203(a) of this title . . . ."

> 37 C.F.R. § 41.203 Declaration.
> (a) Interfering subject matter. An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa.

## Analysis

Under § 1.131(a)(1), prior invention may not be established if the rejection of a patent application claim is based on a U.S. patent which "claims the same patentable invention as defined in § 41.203(a)."

§ 41.203(a) specifies the proper test to determine whether the application claim is to the "same patentable invention" as the patent claim, i.e., "if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." In other words, in making the § 41.203(a) determination, the PTO must ask: 1) whether a claim of the patent, when taken as prior art, anticipates or makes obvious a claim of the application; and 2) whether a claim of the application, when taken as prior art, anticipates or makes obvious a claim of the application. The "same patentable invention" test is often short-handed as the "two-way test" because patentability is determined for both the patent claim and the application claim.

The Examiner did not articulate in the Answer what test was used to reach the conclusion that the application claim and the patent claim were to the "same patentable invention." Therefore, we must scrutinize the Answer to discern on what basis the Examiner reached this conclusion.

On pages 8 of the Answer, the Examiner stated:

> the broadest, most reasonable interpretation of a "nutritional supplement consisting essentially of an effective amount of hyaluronic acid . . . and a food acceptable carrier" (of instant claim 1) includes a nutritional supplement in a gel or paste form.

The Pierce patent claims are drawn to HA in "gel or paste form." The Examiner did not identify specifically what patented Pierce claim was "include[d]" in instant claim 1, nor did the Examiner explain whether it was the application claim or the patented claim which was taken to be the prior art. The Examiner also did not specify whether the claim was "anticipated or rendered obvious" by the subject matter of the other claim, but rather used the non-statutory term "includes." Nonetheless, the most logical

interpretation of the Examiner's statement is that Pierce's claimed gel or paste is "included" in instant claim 1 and therefore is an anticipatory species of the broader instant claim 1. The Examiner repeated this analysis again on pages 10-11 of the Answer.

The Examiner's analysis is defective. First, as discussed above, the Examiner did not identify which Pierce claim was the target of the analysis. Secondly, the Examiner did not use the two-way test required under 37 C.F.R. § 41.203(a), but instead appeared to have applied only the first part of the "two-way" determination, i.e., that a Pierce claim anticipated a claim of the instant application, but did not perform the reverse analysis.

The Examiner also considered Appellant's argument (App. Br. 20-21) that the dosage recited in claims 1 and 20 of the Pierce patent distinguished it from the instant application claims. The Examiner found that the HA amounts recited in instant claim 1 were "within the range" claimed by Pierce. (Ans. 8-9 & 11.) In this case, it appears that the Examiner considered instant claim 1 as the prior art and determined that it was a species ("within the range") of the broader genus recited in claims 1 and 20 of Pierce, and therefore anticipatory to the Pierce claims. Again, the Examiner's analysis is erroneous because the Examiner did not make the reverse determination of whether Pierce claims 1 and 20, when taken as prior art, would anticipate or makes obvious claim 1 of the application.

In sum, the Examiner erred by not properly applying the two-way test for determining whether the instant application and the Pierce patent claims are to the "same patentable invention." Consequently, the Examiner did not meet the burden of showing that prior invention under 37 C.F.R. § 1.131(a) could not be established. As the Examiner did not point to any defect in the

Declaration of Prior Inventorship, we are compelled to reverse the rejection of claims 1, 3-10, and 13.

REVERSED

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